

DATE OUT: 12/AUG/2008

PRODUCT CHEMISTRY REVIEW OF: AN END-USE PRODUCT [X]
DP BARCODE :D339764 RECEIVED DATE 09/MAY/2007 FILE SYMBOL: 264-RNAR
PRODUCT NAME : SC 450 Herboicide MRIDs: 470702-22C ACTION CODE: R01.0
COMPANY NAME: Bayer CropScience, LP FOOD USES [X] DECISION NO.: :378458
PPC NUMBER OF THIS TGA I : 015804

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Technical Review Branch/RD (7505P)

SBM 8/12/08

TO: 23 Joanne Miller/Hope Johnson
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INTRODUCTION:

The primary review of subject product was conducted by the Pesticide Safety Directorate/UK (PSD). The PSD was also the lead country in conducting the primary reviews of Thiencarbazone-methyl technical and Cyprosulfamide safener that was treated as a TGA I. Our secondary/peer reviews of all products were incorporated in reporting tables and uploaded into circa. All primary and peer reviews can be downloaded from circa, a site restricted only to members with user IDs and passwords using the following web site:

<http://circa.europa.eu/Members/irc/sanco/Home/main>

This memorandum applies to subject end-use product focusing on data gaps and/or additional requirements as entered in circa's reportindsg tables. Our reviews in the reporting tables focused on the requirements by the product chemistry discipline as per OPPTS Test Guidelines, Series 830. Other primary or peer reviews were indicated, in the reporting tables, as non-applicable or not required by the product chemistry discipline. In support of this application, the applicant referenced product chemistry data, MRID #470702-22C, a basic CSF dated 22/JAN/2207, a proposed label, Formulator's exemption statement, and Certificate With respect to Citation of Data. .

Group "A" and "B" OPPTS Test Guidelines Series 830:

Except for the requirements listed in this memorandum under Data Gaps, the remaining requirements pertaining to Group "A" and "B" of OPPTS Test Guidelines, Series 830, Product Properties, for subject product have been fulfilled and are adequate.

DATA GAPS:

1. The storage stability, a requirement of GRN #830.6317 was not conducted in compliance with EPA's regulations. It must be repeated for a minimum of one year at ambient warehouse conditions.

2. The proposed HPLC analytical method, LM001803FF7, entitled: "Determination of thiencarbazone-methyl (BYH 18636) and cyprosulfamide (AE 0001789) in formulations by liquid chromatography (HPLC)", will need to be validated by the EPA's laboratory. The applicant should be advised to submit a copy of the method and samples to EPA's laboratory for validation at the following address: EPA's Analytical Chemistry Laboratory, 701 Mapes Road, Fort Meade, Maryland 20755-5350.

Product's Label:

1. SC 450 Herbicide will be used for weed control in crops (field corn, sweet corn, popcorn, and corn grown for silage).
- 2a. The subject product contains 19.231% Thiencarbazone-methyl, Reg. No. 264-RNAN, in the form of Methyl 4[[[4,5-dihydro-3-methoxy-4z-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]-5-methyl-3-thiophenecarboxylate, 97.6% pure, CAS #317815-83-1. The UK was the lead country in conducting the primary reviews for subject end-use product, the TGAI, thiencarbazone-methyl, and the safener, cyprosulfamide.
- 2b. After satisfying the five batch analysis reflecting commercial scale production (refer to #2 under product's CSF) and if the nominal concentration was found to be different from 97.58%, the applicant will need to submit a revised label with an upgraded ingredient statement.
- 3a. The applicant should be advised to list, in product's label, a statement pertaining to "The Physical or Chemical Hazards."
- 3b. The label ingredient statement that reads "Inert Ingredients" must be corrected to read "Other Ingredients."

Products Basic CSF dated 22/FEB/2007

- 1a. The proposed basic CSF dated 22/JAN/2007 was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2).
- 1b. The composition of the product is identical to that reviewed by PSD, the primary reviewer of the lead country. The composition, however, reflects pilot plant production.
- 1c. The applicant should be advised to submit the chemical name, CAS registry number, and percent of each component in an inert ingredient not approved for use in pesticide formulations intended for food uses (refer to Confidential Appendix A).

- 1d The safener cyprosulfamide is currently under review by the Inert Ingredient Branch and, at this time, is not approved to be used in pesticide formulations.
- 1e. Except for the non-cleared ingredients in Findings 1c & 1d above, the remaining ingredients claimed in the basic CSF have been approved for use in pesticide formulations intended for food uses.
- 2. The applicant should be advised to repeat the five batch analysis as per GRN 830.1700 using samples from commercial scale production at the point when production has been stabilized. Analysis must be conducted in full compliance with the GLP requirements of 40CFR§160. If the results are different from those in the trilateral reviews, also reflected in the proposed CSF dated 22/FEB/2007, a revised basic CSF reflecting this analysis will be needed.

CONCLUSIONS:

The TRB has no objections for a conditional registration of subject product as per FIFRA sec. 3(c)(7). After registration of the technical source, thien carbazon methyl (Reg. No. 264-RNAN) and approval of the safener, cyprosulfamide, by the Inert Ingredient Branch, for use in pesticide formulations plus resolving the two data gaps above, #'s 2(b), 3(a) & 3(b) under product's label, and #'s 1(c) & 2 under product's CSF, the TRB will have no objections for acceptance of a revised label/CSF and granting an unconditional registration of subject product as per FIFRA sec. 3(c)(5).

Note to RM:

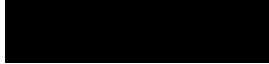
Please note Finding 1(d) above.

Confidential Appendix A

DATE OUT: 07/AUG/2008

DP BARCODE :339764 **PRODUCT NAME :**SC 450 Herboicide **FILE SYMBOL:**264-RNAR
COMPANY NAME: Bayer CropScience, LP **ACTION CODE:** R01.0 **DECISION #:** 378458

Non-Cleared Inert Ingredient for Food Uses:



Inert ingredient information may be entitled to confidential treatment